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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,464	06/22/2001	Gerard H. Llanos	CRD-0929	8413

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EXAMINER	
RAGONESE, ANDREA M	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,464	LLANOS ET AL.	
	Examiner	Art Unit	
	Andrea M. Ragonese	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,16 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/10/03; 10/25/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 14, 2005 has been entered.

Response to Amendment

2. The amendment filed on February 14, 2005 has been entered. Examiner acknowledges that **claim 1** has been amended. Subsequently, **claims 1-8, 16** and **17** are under consideration.

Response to Arguments

3. Applicant's arguments with respect to **claims 1-8, 16** and **17** have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. **Claims 1-8, 16** and **17** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No amendment may introduce new matter into the disclosure of an application after its filing date. See MPEP § 608.04.

Specifically, **claim 1** now recites the claim limitation "a non-polymeric water soluble powder"; however, the originally filed disclosure does not provide evidence that Applicant possessed the newly claimed invention at the time the application was filed. In fact, the original specification of the instant invention discloses "[any] suitable biocompatible material which does not interfere with the drugs, agents, compounds or materials utilized...may be utilized" (page 27, lines 10-20). Applicant is reminded that "any negative limitation or exclusionary proviso must have basis in the original disclosure." See MPEP § 2173.05(i). There is no specific recitation or support for a "non-polymeric" water soluble powder; and therefore, the subject matter added to **claim 1** is considered new matter and must be canceled from the claim. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977); *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), aff'd mem., 738 F.2d 453 (Fed. Cir. 1984); and *Ex parte Parks*, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1-3, 6** and **17** rejected under 35 U.S.C. 102(b) as being anticipated by Donovan et al. (US 5,833,651).

Regarding **claim 1**, Donovan et al. discloses a local drug delivery apparatus comprising:

a medical device **10** for implantation into a treatment site of a living organism (column 5, lines 43-54);

a layer including at least one agent in therapeutic dosages incorporated in a polymeric matrix and affixed to the medical device **10** for the treatment of reactions by the living organism caused by the medical device **10** or the implantation thereof (column 6, line 54 through column 8, line 26); and

a non-polymeric water soluble powder applied to a surface of the polymeric matrix for preventing the layer affixed to a surface of the polymeric matrix fully capable of preventing the layer affixed to the medical device from separating from the medical device prior to implantation of the medical device at the treatment site (column 8, line 66 through column 9, line 28).

Regarding **claims 2-3**, wherein the medical device **10** comprises an intraluminal medical device, such as a stent (column 5, lines 43-54).

Regarding **claim 6**, wherein the at least one agent comprises an anti-coagulant, such as heparin (column 8, lines 45-65).

Regarding **claim 17**, wherein the water-soluble powder comprises an anti-coagulant, such as heparin (column 9, lines 25-28).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. **Claims 1-8** and **17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Chudzik et al. (US 2002/0041899 A1) in view of Donovan et al. (US 5,833,651).

Regarding **claim 1**, Chudzik et al. discloses a local drug delivery apparatus comprising:

a medical device for implantation into a treatment site of a living organism [0003];

a layer including at least one agent in therapeutic dosages incorporated in a polymeric matrix and affixed to the medical device for the treatment of reactions by the living organism caused by the medical device or the implantation thereof [0022]; and

a second layer applied to a surface of the polymeric matrix for preventing the layer affixed to a surface of the polymeric matrix fully capable of preventing the layer affixed to the medical device from separating from the medical device prior to implantation of the medical device at the treatment site [0080].

Chudzik et al. discloses a medical device comprising all the limitations recited in **claim 1**, but does not explicitly recite that the second layer is a non-polymeric water soluble powder. However, the use of this type of coating, such as a non-polymeric water soluble powder, onto a polymeric stent before implantation was known at the time the invention was made. Donovan et al. teaches the use of a second layer, such "powdered heparin [that] can be dusted on the stent" (column 9, lines 25-28).

Further, the instant specification does not demonstrate the criticality of the use of a "powder" since it states, "[any] suitable biocompatible material which does not interfere with the drugs, agents, compounds or materials utilized...may be utilized" (page 27, lines 10-20).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical device of Chudzik et al. by substituting one second layer for an obvious equivalent, such as a layer made from a non-polymeric water soluble powder, because it is well known in the art, as taught by Donovan et al., to use a dusting of "powdered heparin" on an implantable stent.

Regarding **claims 2-3**, wherein the medical device of Chudzik et al. comprises an intraluminal medical device, such as a stent [0065]-[0066].

Regarding **claim 4**, wherein the at least one agent of Chudzik et al. comprises an anti-proliferative [0054]-[0063].

Regarding **claim 5**, wherein the at least one agent of Chudzik et al. comprises an anti-inflammatory [0054]-[0063].

Regarding **claim 6**, wherein the at least one agent of Chudzik et al. comprises an anti-coagulant [0054]-[0063].

Regarding **claim 7**, wherein the at least one agent of Chudzik et al. comprises an immunosuppressant [0054]-[0063].

Regarding **claim 8**, wherein the at least one agent of Chudzik et al. comprises a non-viral gene introducer [0054]-[0063].

Regarding **claim 17**, wherein the water-soluble powder of Donovan et al. comprises an anti-coagulant, such as heparin (column 9, lines 25-28).

12. **Claim 16** is rejected under 35 U.S.C. 103(a) as being unpatentable over Donovan et al. (US 5,833,651), as applied to **claims 1-3, 6** and **17** above, or Chudzik et al. (US 2002/0041899 A1) in view of Donovan et al. (US 5,833,651), as applied to **claims 1-8** and **17** above, and further in view of Schäfer (US 6,407,067 B1). Donovan et al. or Chudzik et al. (US 2002/0041899 A1) in view of Donovan et al. (US 5,833,651) discloses a medical device comprising all the limitations recited in **claim 16**, with the exception of the powder being comprised of an anti-oxidant. However, the use of anti-oxidant as a coating on a stent was known at the time the invention was made. Specifically, Schäfer teaches the use of a powdered antioxidant in combination with a salt of general formula I or II for coating artificial surfaces on medical devices, such as stents (column 4, line 39 through column 5, line 7). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the anti-coagulant powder of Donovan et al. with an antioxidant powder (used in combination with a salt of a thrombin inhibitor) because it is well known in the art, as taught by Schäfer, to use such a coating of this powder on a stent in order to have an "antithrombotic effect" during implantation of the medical device (column 1, lines 2-5).

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese whose telephone number is 571-272-4804**. The examiner can normally be reached on Monday through Friday from 9:00 am until 5:00 pm.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR
June 26, 2005

Henry Bennett
Supervisory Patent Examiner
Group 3700